K061864

510(k) Summary

SEP 18 2006

Device Trade Name: Non Sterile Surgical Mask

Name and Address of Manufacturer:
Dukal Corporation
5 Plant Ave
Hauppauge, NY 11788

Establishment Registration: 2435946

Contact Person:
Patrick J. Lamb
Vice President International Operations
5 Plant Ave.
Hauppauge, NY 11788

Device Classification Name: Mask, Surgical

Classification Panel: Class II, §878.4040

Classification Advisory Committee: General and Plastic Surgery

Product Code: FXX

Recognized Performance Standard:
ASTM 2100-04
Refer to submission for applicable standards

Predicate Devices 510(k) Number
1. A.R. Medicom K051291

2. ValuMax International (K040333

Intended Use: The Dukal medical / surgical masks are indicated as a protective nose and mouth covering for healthcare workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situation where there is a risk of microorganism, body fluid and particulate aerosol transfer.

510(k) Statement: A 510(k) statement for this device, as required by 21 CFR 93, is replaced with this 510(k) summary.

Truthful and Accurate Statement: A Truthful and accurate statement as required by 21 CFR §807.87(j) may be found in the submission in Exhibit A

Labeling: Samples of proposed labeling may be found in the submission in Exhibit B

Device Description: Dukal Surgical Masks are pleated 3 – ply masks. Inner and outer layers are made of either medical grade tissue or 100% spun-bond polypropylene. Middle layer is made of 100% melt blown polypropylene filter. Ear loops are made of soft latex free elastic loops. The nose piece for all Dukal Masks is a malleable aluminum wire. Masks with splash visors have an anti fog treated plastic shield attached to masks. All of the material used in the construction of the Dukal face masks are being used in currently marketed devices (see predicate information)

Performance Characteristics

Item	Test Method	Dukal	Medicom K051291
Inner Layer	Raw material Specifications	100% Spun-bond polypropylene or medical grade tissue (25 gsm)	Same
Outer Layer	Raw material Specifications	100% Spun-bond polypropylene or medical grade tissue (16gsm)	100% Spun-bond polypropylene or medical grade tissue (14gsm)
Middle Layer	Raw material Specifications	100% melt blown polypropylene filter media (25 gsm)	Same
Ear Loop	Raw material Specifications	Soft latex free elastic loops and ties (40 gsm)	Latex Free Elastic Loops and ties 38 gsm
Nose Piece	Raw material Specifications	Malleable aluminum wire	same
Plastic Shield	Raw material Specifications	ATFF-High Impact 0.10mm	same
Fluid Resistance Performance (mmHg)	ASTM F1862-05 Pressure at 80mm Hg	30 out of 32 passed	19 out of 32 passed
Particulate Filtration Efficiency Performance (%)	ASTM2299	98.3%	98.7%
Bacterial Filtration Efficiency Performance (%)	ASTM F2101-01 ASTM F2100-04	99.9%	99.8%

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Item	Test	Dukal	Medicom K051291
Differential Pressure (Delta-P) (mmH20/cm2)	ASTM F2101-01 MIL-M-36945C 4.4.1.1.1 Method 1	2.28 (ave) mmH_2O/cm^2	2.28 (ave) mmH_2O/cm^2
Flammability class 1	ASTM F2101-01 MIL-M-36945C 4.4.1.1.1 Method 1	No Flame Spread Class 1	No Flame Spread Class 1
Mask Styles		Tie, Ear Loop and mask with fluid shield	Tie, Ear Loop and mask with fluid shield
Color		Blue	Blue
Layers		3	3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 8 2006

Mr. Patrick J. Lamb
Vice President International Operations
Dukal Corporation
5 Plant Avenue
Hauppauge, New York 11788

Re: K061864
Trade/Device Name: Dukal Surgical Face Masks
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: August 18, 2006
Received: September 13, 2006

Dear Mr. Lamb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

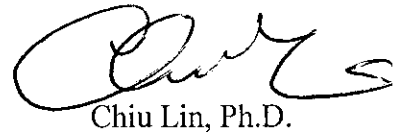
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061864

Device Name: Dukal Surgical Face Masks

Indications for Use:

The Dukal medical / surgical masks are indicated as a protective nose and mouth covering for healthcare workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situation where there is a risk of microorganism, body fluid and particulate aerosol transfer.
This covers our current catalog numbers (these numbers can change with updated revisions to the catalog):

Catalog Number	Face Mask Description	Model Type
1530	Face Mask	Ear Loops
1540	Face Mask	Ties
1560	Face Mask	Fluid Shield with Ear Loop
1570	Face Mask	Fluid Shield with Ties

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shula A Murphy MD 9/8/06
...ion Sign-Off)
...ion of Anesthesiology, General Hospital,
...ction Control, Dental Devices
...(k) Number: K061864